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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/445,963 | 12/16/1999 | TOHRU TANAKA | Q57226 | 1604 |

7590 05/20/2003

SUGHRUE MION ZINN MACPEAK & SEAS
2100 PENNSYLVANIA AVENUE NW
WASHINGTON, DC 20037

EXAMINER

YU, MISOOK

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1642 | 24 |

DATE MAILED: 05/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/445,963 | TANAKA ET AL. | |
| | Examiner | Art Unit | |
| | MISOOK YU, Ph.D. | 1642 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 26 February 2003.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 10 and 11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 10 and 11 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.

- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ . |

The Examiner of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Misook Yu.

DETAILED ACTION

Receipt of the Response (Paper No. 23) filed on 2-26-2003 is acknowledged.

Claims 10 and 11 are pending and examined on merits.

Claim Rejections - 35 USC § 103

Claims 10 and 11 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Kennedy et al (1994, ACS Symp. Ser., pp.291-302) in view of Jichlinski, et al (1996, Pro. SPIE-Int. Soc. Opt. Eng. pp.340-347), Kajiwara (1990, JP 02111747), and Jaffe, et al (1990, Biochemistry, pp.8345-50).

Applicant argues that the instant invention is drawn to method administering isotope labeled ALA to the living body of a subject and subjected therein to a biochemical reaction, and malignant tumors are then detected by the distribution of the isotope in the living body of the subject without any separation of the compound. This argument is not persuasive because Jichlinski et al teach method of administering labeled 5-ALA to the living body of a subject and subjected therein to a biochemical reaction in order to detect malignant tumors, and Jaffe et al teach detailed NMR techniques for detecting the biochemical product occurred in the living body of a subject who received 5-ALA and Kajiwara teach radiolabeled 5-ALA is useful for diagnosis, thus every limitation of the diagnosing part of the claims were known in the art before the effective filing date of the instant invention.

Applicant further argues that even if the references were to be combined, one of ordinary skill in the art would not be reasonably motivated to expect a reasonable chance of success that **the amount of the isotope label could be measured in a living body** and that the result could be applied to medical techniques at tissue in the present claims. This argument is not persuasive, either because the specification at 25-26 and the NMR data at Fig. 1, **the amount of the isotope label is not measured in a living body**, but measured outside of a living body, using the same NMR techniques taught by Jaffe et al.

Applicant further argues that in Kennedy, light exposure is essential for the detection of malignant tumors, and in distinction, diagnosis of the instant invention can be carried out operations involving a combination of an isotope and NMR or MRI. This argument is not persuasive, either because Kennedy teach cancer therapy, not cancer diagnosis, and the claims do not say anything about operations involving a combination of an isotope and NMR or MRI and the specification does not teach anything about **operations involving a combination of an isotope and NMR or MRI.**

Applicant further argues that one of ordinary skill would not be motivated to combine Kennedy et al and Kajiwara and/or Jaffe because one teaches medical treatment and the other teaches structural studies. This argument is not persuasive, either because Kajiwara teaches isotope labeled 5-ALA could be useful for diagnosis [of cancer] in light of Jichlinski et al who teach administration of 5-ALA to living body of a subject could be used to detect presence of cancer (see the abstract) and Jaffe et al who teach technical details of NMR using ¹³C and ¹⁵N labeled 5-ALA. Combination of the three references teach that ¹³C and/or ¹⁵N chemical shift in NMR can be used to detect cancer in a patient after administering of isotope labeled 5-ALA with the reasonable expectation of success. One would be motivated to combine the cited references because cancer diagnosis is mandatory before cancer treatment. It is the Office position that the secondary references as a whole teach a method of diagnosing cancer using 5-ALA and Kennedy et al who teach method of cancer treatment using the same compound; once cancer is confirmed, then light is provided to activate the biochemical reaction product preferentially accumulated in cancer tissues to kill cancer cells, thus catching two birds with a single stone.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 703-308-2454. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Misook Yu
May 16, 2003


ANTHONY C. CAPUTA
SUPERVISOR, IMAGE PROCESSING
TECHNOLOGY DIVISION